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EXAMINER	
HAND, MELANIE JO	

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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RAY L. PICKUP, CLEMENT C. LO, and
WILLIAM D. NOONAN

Appeal 2009-008532
Application 10/791,974
Technology Center 3700

Before LINDA E. HORNER, MICHAEL W. O'NEILL, and
FRED A. SILVERBERG, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Ray L. Pickup et al. (Appellants) seek our review under 35 U.S.C. § 134 of the Examiner's decision rejecting claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, 148-150, and 183-185, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b).

SUMMARY OF DECISION

We REVERSE.

THE INVENTION

Appellants' claimed invention is directed to "cutaneous delivery of a bioactive composition using a jet dispenser, such as a piezoelectric or thermal jet dispenser, for instance of a construction used in the inkjet printing arts." Spec. 4, para. [21]. Claims 83 and 91, reproduced below, are representative of the subject matter on appeal.

> 83. A method of administering a bioactive composition to a subject, the method comprising:
>
> applying to a cutaneous surface of the subject a jet dispenser comprising a container holding the bioactive composition;
>
> dispensing the bioactive composition in droplets from the dispenser through at least one orifice toward the cutaneous surface such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface or a dermal patch thereon; and
>
> retaining the bioactive composition in prolonged contact with the cutaneous surface.

91. A method of administering a bioactive composition to a subject, the method comprising:

applying a cutaneous patch to skin of the subject; and

dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of the patch.

THE EVIDENCE

The Examiner relies upon the following evidence:

Meyerson	US 5,179,947	Jan. 19, 1993
Rogers	US 5,480,062	Jan. 2, 1996
Jacobsen	US 5,860,957	Jan. 19, 1999
Svedman	US 6,048,337	Apr. 11, 2000
Hayes	US 6,325,475 B1	Dec. 4, 2001

THE REJECTIONS

Appellants seek review of the following rejections:

1. The Examiner rejected claims 83-85, 87-89, 91-95, 98, 99, 102, 105-107, 118, 123, 126, 131, 136, 140, 141, and 183-185 under 35 U.S.C. § 102(b) as being anticipated by Svedman.
2. The Examiner rejected claims 86, 96, 97, 119, 120, 127, 128, and 148-150 under 35 U.S.C. § 103(a) as being unpatentable over Svedman.
3. The Examiner rejected claims 90 and 100 under 35 U.S.C. § 103(a) as being unpatentable over Svedman and Rogers.
4. The Examiner rejected claims 103 and 104 under 35 U.S.C. § 103(a) as being unpatentable over Svedman and Hayes.
5. The Examiner rejected claims 108 and 109 under 35 U.S.C. § 103(a) as being unpatentable over Svedman and Jacobsen.

6. The Examiner rejected claims 124, 125, 132, and 133 under 35 U.S.C. § 103(a) as being unpatentable over Svedman and Meyerson.

ISSUES

The issues presented by this appeal are:

Does the embodiment of Figure 79 of Svedman disclose dispensing a bioactive composition in droplets through an orifice in a dispenser "such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface or a dermal patch thereon" as called for in claim 83?

Does the embodiment of Figure 63 of Svedman disclose "dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of [a cutaneous] patch" as called for in claim 91?

ANALYSIS

Rejections of claims 83-90, 102-104, 108, 118-120, 123-125, 136, 140, 148, 149, and 183

Appellants contend that the rejection of independent claim 83 and the rejections of all of the claims depending from claim 83 are in error because Svedman does not teach or suggest the airborne dispensing called for in claim 83. Br. 11-20.

The Examiner found that Svedman discloses airborne dispensing in column 35, lines 51-63. Ans. 4. In particular, the Examiner found that "the pump 177 of Figure 79 is a thermal droplet generator with an array of nozzles (at least one orifice) that dispenses a drug (bioactive composition) in

droplets ... toward drug cell 175 where the drug will subsequently be administered to the cutaneous surface." Ans. 21. The Examiner found that "when droplets are formed, air is also necessarily present, especially since the droplets are conveyed toward the drug cell 175, thus they are airborne, as air is necessarily present in the conduit." *Id.*

Figure 79 of Svedman is "a schematic sectioned elevation of an arrangement in which two separate implementing devices are utilized for sampling and drug delivery." Svedman, col. 13, ll. 59-61; *see also* Svedman, col. 35, ll. 43-45. Svedman describes that enclosures 172 and 173 provide sampling and drug delivery cells 174 and 175, respectively, arranged in registration with skin sites 170 and 171, respectively. Svedman, col. 35, ll. 43-48. Svedman describes that a control unit 169 actuates a pump 177 to deliver metered quantities of drug to drug delivery cell 175 from a reservoir 159. Svedman, col. 35, ll. 51-53. Svedman further describes the pump 177 as follows:

> The pump 177 may for example be a micro pump of the type normally used in bubble jet ink printers and relying upon the pulsed application of heat to expel discrete quantities of liquid within capillaries by the formation of vapour bubbles. Such a micro pump, in this case typically referred to as a thermal droplet generator, an array of nozzles is provided, each having an associated liquid channel of nanolitre volume with a heating element associated with each channel, the nozzle outlet dimensions being of the order of 40 microns diameter.

Svedman, col. 35, ll. 54-63. Svedman does not appear to disclose that the nozzles of pump 177 are positioned in or contiguous to drug delivery cell 175. Rather, Figure 79 of Svedman appears to disclose a conduit disposed

between micro pump 177 and drug delivery cell 175. As shown in Figure 79, the conduit has a first leg that extends downwardly from the exit of micro pump 177, and a second leg disposed at 90 degrees to the first leg and that extends to a right side entry port in enclosure 173 of drug delivery cell 175. Enclosure 173 appears to have an opening at the center of its bottom side directly above the skin site 171. Svedman, fig. 79.

Claim 83 calls for the dispensed droplets to become airborne upon leaving the orifice and remain airborne until coming into contact with the cutaneous surface or dermal patch thereon. We fail to see how the droplets dispensed from Svedman's pump 177 remain airborne from the point at which they leave the pump 177 until they come into contact with the patient's skin. Because the pump 177 dispenses the droplets into a conduit and the droplets must travel through a bend in the conduit to reach the drug delivery cell 175, it seems probable that the droplets touch the sides of the conduit as they travel from the pump 177 to the drug delivery cell 175. The Examiner's finding that Svedman's apparatus depicted in Figure 79 anticipates the airborne dispensing step of claim 83 is based on speculation. As such, we cannot find by a preponderance of the evidence that Svedman anticipates claim 83.

The rejections of the remaining claims that depend from claim 83 likewise rely on this same finding of fact. Accordingly, we will not sustain the rejection of claim 83 as anticipated by Svedman, or the rejections of dependent claims 84-90, 102-104, 108, 118-120, 123-125, 136, 140, 148, 149, and 183.

Rejections of claims 91-100, 105-107, 109, 126-128, 131-133, 141, 150, 184, and 185

Appellants contend that the rejection of independent claim 91 and the rejections of all of the claims depending from claim 91 are in error because Svedman does not disclose use of an inkjet dispenser for dispensing a bioactive composition above a patch, and does not disclose ejection of a bioactive composition through an inkjet dispenser orifice that is spaced from and directly above the face of a patch, as called for in claim 91. Br. 21-24.

The Examiner found that Svedman discloses dispensing a bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of site 8 or the patch 121 in the form of aperture 6. Ans. 6 (citing Svedman, figs. 63, 65, and 66 and col. 31, ll. 12-15). In particular, the Examiner found that the embodiment of Figure 63 is identical to the device 1 shown in Figures 34 through 37 except for the application of a patch 121 after de-epithelialisation. Ans. 22. Thus, the Examiner found that "the patch 121 must be present over the site prior to delivery of the drug, and therefore the drug is necessarily delivered from device 1 to the patch 121." *Id.* The Examiner further found that "the orifice for delivery, aperture 6, is necessarily spaced from a face of the patch 121 in order for the drug to be able to be administered to the patch 121, rather than being trapped and or pooling at the orifice 6." *Id.*

We fail to see in the embodiments of Figures 34-37 or Figures 63-69 of Svedman any disclosure of dispensing the bioactive composition through the orifice of an inkjet dispenser. Svedman discloses that "[t]he device 1 is

modified in FIG. 63 to include a patch applicator 120 which is operable to apply a patch 121 to the area of skin 8 following de-epithelialisation while the device 1 remains in situ." Svedman, col. 31, ll. 12-15. The device 1 is shown schematically in Figures 34-37 of Svedman and described in column 23, line 37 – column 25, line 5. As described with respect to Figures 34-37, in use, suction is applied to a suction cup 9 of device 1 to form a suction blister 17 on the patient's skin 4. Svedman, col. 24, ll. 1-7; fig. 34. A blade 18 is then moved arcuately so as to cut through the suction cup 9, wherein the roof of the suction blister 17 remains adhered to a removable portion 20 of the suction cup 9. Svedman, col. 24, ll. 16-23; fig. 35. Following severing of the suction cup 9, the removable portion 20 is removed and a rotatable portion 5 of device 1 is rotated into a second position so that an outlet port 22 of reservoir 11 is brought into registration with an aperture 6 in base 3 of device 1. Svedman, col. 24, ll. 24-25 and ll. 39-42; fig. 36. Drug 12 within the reservoir 11 then enters a chamber 16 and comes into contact with the de-epithelialised area of skin 8. Svedman, col. 24, ll. 48-51. On completion of the drug delivery phase, the rotatable portion 5 is rotated to a third position so that outlet port 22 of the reservoir 11 is closed. Svedman, col. 24, ll. 55-59; fig. 37.

In the embodiment of Figures 63-69, the device 1 is modified to include a patch applicator 120 in lieu of the reservoir 11. The patch applicator 120 is operable to apply a patch 121 to the area of skin 8 following de-epithelialisation. Svedman, col. 31, ll. 12-15; fig. 63. Svedman discloses that once the patch 121 is applied to the patient's skin via

modified device 1, then the adhesive tape 133 is dissociated from the skin 4 and the base 3 is dissociated from the skin so that the device 1 can be lifted clear. Svedman, col. 32, ll. 43-48. Svedman discloses that patch 121 may be a self-contained means for administering a supply of drug (e.g., a porous pad impregnated with a liquid for diffusion out of the pad and onto the de-epithelialised area of dermis), or the patch 121 may comprise a permeable membrane through which a liquid drug can be diffused from a conventional skin patch applied over patch 121. Svedman, col. 32, ll. 51-61.

It does not appear from the description provided in Svedman of the modified device 1 of Figure 63, that this modified device is used to administer the drug to patch 121. Nor does it appear from the disclosure in Svedman that an inkjet dispenser is used to administer the drug to patch 121. Rather, the patch 121 may either be impregnated with the drug or receive the drug from a conventional skin patch applied over patch 121. Thus, the Examiner's finding that Svedman's Figure 63 discloses the step of dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of the patch, as called for in claim 91, is in error.

The rejections of the remaining claims that depend from claim 91 likewise rely on this same erroneous finding of fact. Accordingly, we will not sustain the rejection of claim 91 as anticipated by Svedman, or the rejections of dependent claims 92-100, 105-107, 109, 126-128, 131-133, 141, 150, 184, and 185.

CONCLUSIONS

The embodiment of Figure 79 of Svedman does not disclose dispensing a bioactive composition in droplets through an orifice in a dispenser "such that the bioactive composition becomes airborne upon leaving the at least one orifice and remains airborne until coming into contact with the cutaneous surface or a dermal patch thereon" as called for in claim 83.

Thee embodiment of Figure 63 of Svedman does not disclose "dispensing the bioactive composition from an inkjet dispenser by ejection through an orifice spaced from and directly above a face of [a cutaneous] patch" as called for in claim 91.

DECISION

The decision of the Examiner to reject claims 83-100, 102-109, 118-120, 123-128, 131-133, 136, 140, 141, 148-150, and 183-185 is reversed.

REVERSED

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